IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| IDENIX PHARMACEUTICALS LLC and UNIVERSITA DEGLI STUDI DI CAGLIARI,<br><br>Plaintiffs,<br><br>v.<br><br>GILEAD SCIENCES, INC.,<br><br>Defendant. | C.A. No. 14-846-LPS |

**PLAINTIFFS' MOTION FOR JUDGMENT AS A MATTER OF LAW**

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## I. INTRODUCTION

Plaintiffs move for judgment as a matter of law that Gilead has failed to show by clear and convincing evidence that the asserted claims of U.S. Patent No. 7,608,597 are invalid for lack of written description, lack of enablement, lack of utility, and anticipation or obviousness. Plaintiffs move for judgment as a matter of law that the '597 patent is entitled to a priority date of May 23, 2000. Finally, Plaintiffs move for judgment that Gilead's damages theory fails as a matter of law.

## II. LEGAL STANDARD

Pursuant to Federal Rule of Civil Procedure 50, a court may render judgment as a matter of law after the moving party is fully heard on an issue at trial if there is no legally sufficient evidentiary basis for a reasonable jury to find for the party opposing the motion on that issue. *Walter v. Holiday Inns, Inc.*, 985 F.2d 1232, 1238 (3d Cir. 1993).

## III. ARGUMENT

### A. Gilead Failed To Proffer Evidence Sufficient To Prove The Asserted Claims Of The '597 Patent Are Invalid For Lack Of Written Description

Gilead has failed to present legally sufficient evidence for a jury to find that persons of ordinary skill in the art would find the '597 patent invalid for lack of written description. The party raising a written description challenge must submit clear and convincing evidence of invalidity. *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319 (Fed. Cir. 2003). That party also must show that the specification fails to describe the claimed invention in sufficient detail to permit one skilled in the art to reasonably conclude that the inventor had possession of the invention as of the filing date. *Moba*, 325 F.3d at 1319. "[I]psis verbis disclosure is not necessary…." *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996). And where, as here, the claim recites a genus (or subgenus), there is no "heightened requirement

to provide a nucleotide-by-nucleotide recitation of the entire genus." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) (en banc); *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997) ("[E]very species in a [claimed] genus need not be described" to provide written description support.). Indeed, no "particular form of disclosure" is required. *Ariad*, 598 F.3d at 1352, 1368-69. Rather, the specification may provide "a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Id*. at 1350. These and other types of "blaze marks" are sufficient. *In re Ruschig*, 379 F.2d 990, 993-95 (C.C.P.A. 1967).

At trial, the evidence presented by Gilead did not meet the necessary threshold to satisfy Gilead's burden of proving lack of written description by clear and convincing evidence. Instead, the evidence in the record demonstrated that the '597 specification adequately describes the class of compounds used within the asserted claims of the '597 patent. Dr. Meier testified that the specification teaches a method of treating hepatitis C virus by using a class of 2'-methyl ribonucleosides that achieve HCV polymerase inhibition. Dr. Meier also testified the specification discloses a subgenus that is not limited to OH in the down position and representative number of species falling within that subgenus. Further, there are additional blaze marks including preferred embodiments and experiments pointing the skilled artisan to not only the members of the class but also the defining 2'-methyl up feature of the class. Significantly, the evidence demonstrates that artisans in the field at the time, including the scientists at Pharmasset, recognized those blaze marks. Gilead opposed by contending that later developments somehow resulted in lack of written description support, a legally irrelevant contention. *In re Koller*, 613 F.2d 819, 823 (C.C.P.A. 1980). Accordingly, Gilead cannot as a

matter of law meet its high burden to show the '597 patent lacks written description. No reasonable jury can find for Gilead in view of this evidence.

### B. Gilead Failed To Proffer Evidence Sufficient To Prove The Asserted Claims Of The '597 Patent Are Invalid For Lack Of Enablement

Gilead has failed to present legally sufficient evidence for a jury to find that it would take undue experimentation to make and use the claimed invention. "Under the enablement requirement of § 112, 'the specification must enable one of ordinary skill in the art to practice the claimed invention without undue experimentation.'" *Transocean Offshore Deepwater Drilling*, 699 F.3d at 1355; *see also In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988). "The key word is undue, not experimentation." *Wands*, 858 F.2d at 737 (quotation marks omitted); *see also Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1188-89 (Fed. Cir. 2014) (stating that only "[a]fter the challenger has put forward evidence that some experimentation is needed to practice the patented claim [the Wands factors provide factual considerations] that a court may consider when determining whether the amount of that experimentation is either 'undue' or sufficiently routine"). "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *Id.* The following factors are relevant to determining if a disclosure requires undue experimentation: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.*

Plaintiffs have presented evidence that the field of nucleoside synthesis was very well developed by the relevant date. Further, that the field of testing nucleosides as polymerase inhibitors also was well understood. Thus the disclosures in the specification show how to make

and use compounds within the scope of the claims. These include complete synthetic schemes for making specific compounds that are encompassed by the asserted claims. Furthermore, Dr. Meier testified that the synthetic routes disclosed in the patent enable the skilled artisan to make the full class of compounds encompassed by the asserted claims. Gilead, on the other hand, points only to the alleged failures of a chemist at Idenix to make a single embodiment of a compound falling within the scope of the asserted claims. While that chemist worked to make a 2'-methyl, 2'-fluoro ribonucleoside in 2002-2003, Gilead proffered no evidence this chemist had the '597 patent in hand when he was performing his experiments. To the contrary, the evidence is that he did not have the '597 patent in hand. Still further, this later development work (whether by Plaintiffs or Pharmasset) cannot properly form the basis for an enablement defense. *See, e.g.*, *In re Hogan*, 559 F.2d 595, 606 (C.C.P.A. 1977). Thus, the work Plaintiffs' conducted is irrelevant to the inquiry whether the patent specification enables one of ordinary skill in the art to practice the claimed invention without undue experimentation.

On the other hand, the evidence also demonstrates that at the same time another scientist at Pharmsset – with the '597 patent specification in hand – was able to make the same 2'-methyl, 2'-fluoro ribonucleoside embodiment without any assistance and without any difficulty. Accordingly, the only evidence in the record of an individual following the disclosure of the '597 patent to make a 2'-methyl, 2'-fluoro ribonucleoside demonstrates that Gilead cannot meet its burden to show by clear and convincing evidence that the '597 patent specification lacks an enabling disclosure.[1]

Accordingly, Plaintiffs are entitled to judgment as a matter of law that the '597 patent has

[1] In addition, the experts for both parties agreed that there are a limited number of 2'-methyl ribonucleosides capable of treating hepatitis C virus infections.

an enabling disclosure.

### C. Gilead Failed To Proffer Evidence Sufficient To Prove The Asserted Claims Of The '597 Patent Are Invalid For Lack Of Utility

Gilead has failed to present any evidence by which a jury could find a lack utility for the '597 patent. "The question of whether a specification provides an enabling disclosure under § 112, ¶ 1, and whether an application satisfies the utility requirement of § 101 are closely related." *Swartz*, 232 F.3d at 863. "If a claimed invention does not have utility, the specification cannot enable one to use it." *In re Brana*, 51 F.3d 1560, 1564 (Fed. Cir. 1995). Furthermore, evidence of infringement of a claim supports the utility of such infringed claim. "It is axiomatic that one who appropriates the teachings of a patent may not deny the utility of the invention." *E.I. du Pont de Nemours & Co. v. Berkley & Co.*, 620 F.2d 1247, 1258-59 (8th Cir. 1980) (holding that the infringer, was estopped from asserting that [the infringed] claims were invalid for lack of utility); *Tapco Prods. Co. v. Van Mark Prods. Corp.*, 446 F.2d 420, 428 (6th Cir. 1971) ("one who appropriates the teachings of a patent may not deny the utility of the invention"); *Raytheon*, 724 F.2d at 959 ("A correct finding of infringement of otherwise valid claims mandates as a matter of law a finding of utility under § 101.") (citing and following *Du Pont* and *Tapco*).

Here, Gilead has proffered no evidence the invention claimed in the '597 patent lacks utility. Moreover, Gilead conceded infringement. Accordingly, as a matter of law, Gilead cannot meet its burden to show lack of utility by clear and convincing evidence.

### D. The Asserted Claims Of The '597 Patent Are Entitled To The May 23, 2000 Priority Date Of The '585 Provisional Application

Plaintiffs are entitled to a priority date of May 23, 2000 as a matter of law. First, for the same reasons the '597 patent satisfies the written description and enablement requirements, the '585 provisional application does as well. The '585 provisional application provides the same

blaze marks pointing to the class of compounds used by the asserted method claims of the '597 patent. It identifies the disease to be treated and the target to achieve it. It proves compositions and methods for use in a host. Finally, the USPTO determined the '597 is entitled to a May 23, 2000 priority date. In any event, to the extent the '585 provisional application does not satisfy the written description and enablement requirements, then Plaintiffs nevertheless are entitled to the May 23, 2000 priority date because they indisputably conceived of their invention by that date and worked diligently to reduce it to practice by their May 23, 2001 non-provisional filing date. Indeed, through Drs. Gosselin and Standring, Plaintiffs proffered overwhelming evidence of their reasonably continuous activity leading up to the May 2001 non-provisional filing date. Gilead offered no evidence to rebut Plaintiffs' diligence. Accordingly, regardless of any finding regarding the '585 provisional application's disclosure, Plaintiffs are entitled to their May 23, 2000 priority date.

### E. Plaintiffs Are Entitled To Judgment As A Matter Of Law On Defendant's Defenses Based On Merck Work And Patents

Gilead invokes 35 U.S.C. §§ 102(e)(2) or 102(g) to contend that some Merck work and/or patents are invalidating prior art.[2] Section 102(e)(2) covers U.S. patents where the application was filed before the priority date of the asserted patent. *See* 35 U.S.C. § 102(e)(2) (pre-AIA). Section 102(g) covers prior inventions "made in this country by another inventor who had not abandoned, suppressed, or concealed it." 35 U.S.C. § 102(g) (pre-AIA). Under either provision, priority is established if the inventor reduced an invention to practice first or was first to conceive and then was diligent in reducing to practice. *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 252 F.3d 1306, 1314 (Fed. Cir. 2001) (vacated on other grounds). Gilead bears

[2] Idenix preserves its objections to these late disclosed defenses. Idenix does not waive any objection by this motion.

the burden, at all times, to prove its prior invention defenses, by clear and convincing evidence. *See Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1037-38 (Fed. Cir. 2001)

Invention requires conception and reduction to practice by a person: "Making the invention requires conception and reduction to practice." *Solvay S.A. v. Honeywell Int'l Inc.*, 742 F.3d 998, 1000 (Fed. Cir. 2014). "Conception defines the legally operative moment of invention under § 102(g). It is the 'formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.'" *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1063 (Fed. Cir. 2005) (quoting *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986)). Conception requires "both (1) the idea of the invention's structure and (2) possession of an operative method of making it." *Invitrogen*, 429 F.3d at 1063 (citing *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991)).

For an invention to exist, the alleged prior inventor must have appreciated what he invented. "There must be *contemporaneous recognition and appreciation* of the invention . . . ." *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 593 (Fed. Cir. 1997) (emphasis in original); *see also Genentech, Inc. v. Chiron Corp.*, 220 F.3d 1345, 1352 (Fed. Cir. 2000) (Reduction-to-practice prong requires "recognition and appreciation that the tests were successful."); *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1063 (Fed. Cir. 2005) ("Conception requires that the inventor appreciate that which he has invented.").

Gilead must, in addition to establishing the quintessential markers of invention of conception and reduction to practice, show that the test "performed a process that met all the limitations" of the asserted claims. *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316,

1332, 1337 (Fed. Cir. 2001). Thus, Gilead must show that the 1998 BVDV test performed "[a] method for the treatment of a hepatitis C virus infection."

In determining priority, "there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other." 35 U.S.C. § 102(g) (pre-AIA). Diligence is measured "from a date just prior to the other party's conception to . . . the date of reduction to practice by the party first to conceive," which is known as the "critical period." *Monsanto Co. v. Mycogen Plant Sci., Inc.*, 261 F.3d 1356, 1363 (Fed. Cir. 2001). To establish diligence, "the basic inquiry is whether . . . there was reasonably continuing activity to reduce the invention to practice." *Tyco Healthcare Grp. LP v. Ethicon Endo-Surgery, Inc.*, 774 F.3d 968, 975 (Fed. Cir. 2014) (citation omitted).

**1. Gilead failed to prove by clear and convincing evidence that Merck's 1998 BVDV testing is prior art**

Gilead failed to adduce clear and convincing evidence that Dr. Wolanski's 1998 testing of a 2'-methyl compound (L765) in the BVDV assay is a conception or reduction to practice of any claim of the '597 patent. Gilead also failed to prove by clear and convincing evidence that any alleged invention was not abandoned, suppressed, or concealed. Dr. Olsen, the leader of the Merck/Isis collaboration from 1998 to 2003, testified that his group did not discover that L765 was useful for treating hepatitis C virus prior to the fall 2000. This testimony alone should dispose of Gilead's defense.

But additional evidence supports the same conclusion. Dr. Olsen testified that at the time of the 1998 testing, his group (including Dr. Wolanski) did not know if methyl was in the 2'-up or 2'-down position. Consequently, ***no one*** could have known whether that compound fell within the structural limitations of the claims of the '597 patent (which require methyl at the 2'-

up position). Dr. Olsen also testified that after the 1998 testing, no follow-up work was done on L765 until Merck's independent discovery of the anti-HCV activity of a 2'-methyl up ribonucleoside in fall 2000. Dr. Duffy testified to this fact as well. Likewise, Gilead's expert, Dr. Seeger, testified that he is not aware of any testing Merck ran on L765 between December 1998 and May 2000.

As to Dr. Wolanski, Gilead's expert, Dr. Seeger, testified that he did not know what anyone at Merck (including Dr. Wolanski) thought about whether the results of the 1998 BVDV test was an invention for the treatment of hepatitis C virus. Dr. Seeger further testified that Dr. Wolanski may not have even known of the structure of the compound he tested consistent with Dr Olsen's testimony that no one on his team at Merck knew the structure until after Sept 2000. And Dr. Seeger testified that he personally did not believe that the 1998 BVDV test was a reduction to practice of a method of treating hepatitis C virus.

**2. Gilead failed to prove by clear and convincing evidence that Merck's 2000 work and patents are prior art**

Gilead's defenses based on Merck's September (and August) 2000 testing of L765 and on Merck's U.S. Patent No. 7,105,499 ("the '499 patent"), which claims priority to Merck's January 2001 provisional application, also fail as a matter of law. As an initial matter, as shown above, Plaintiffs are entitled to their May 23, 2000 priority date making Merck's work beginning in August 2000 and its '499 patent, with an earliest possible priority date of January 2001, too late to qualify as prior art. As stated above, the USPTO agreed the '597 is entitled to a May 23, 2000 priority date. Even assuming that Plaintiffs are not entitled to a May 23, 2000 priority date, the asserted art is too late. There is no dispute that Drs. Sommadossi and La Colla conceived of their invention by May 2000, before Merck did in September (or August) 2000. Moreover, the testimony and evidence presented by Drs. Gosselin and Standring demonstrate that at the behest

of Dr. Sommadossi, Plaintiffs diligently worked on the invention from prior to Merck's September (and August) 2000 conception up to the inventors' May 23, 2001 filing of their non-provisional application. Gilead did not challenge this evidence at trial, and certainly did not attempt to prove (by clear and convincing evidence) that the inventors and those acting at their direction were not diligent. Thus, the 2000 testing and Merck's '499 patent with an earliest possible priority date of January 2001 are not prior art under Sections 102 or 103 for either possible priority date of Plaintiffs.

Additionally, Gilead has failed to prove that any Merck patent is entitled to the priority date of Merck's January 2001 provisional application. "For a patent to claim priority from the filing date of its provisional application," the provisional "must contain a written description of the invention and the manner and process of making and using it" and "enable an ordinarily skilled artisan to practice the invention claimed in the non-provisional application." *Dynamic Drinkware LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1381 (Fed. Cir. 2015). Gilead adduced no evidence at trial that Merck's '499 patent (or any other Merck patent) is entitled to claim priority to the January 2001 provisional application. Indeed, in the Northern District of California litigation, Gilead has steadfastly maintained that the '499 patent is invalid for lack of enablement and written description, and that that its claims are not supported by the January 2001 provisional application. In any event, Gilead offered no evidence at trial in support of the '499 patent qualifying as prior art to the '597 patent. Even if it had, Gilead has failed to demonstrate by clear and convincing evidence that any of the asserted claims are anticipated by or obvious over Gilead's asserted prior art. No reasonable jury could find from Gilead's perfunctory case at trial that it has proven invalidity much less satisfied its clear and convincing burden of proof. Likewise, in light of secondary considerations of non-obviousness introduced

at trial including commercial success, an unmet but long-felt need, surprising results, and other objective indicia, no reasonable jury could find in Gilead's favor. Accordingly, Plaintiffs are entitled to judgment as a matter of law that the '597 patent is neither anticipated nor obvious in light of any of Gilead's so-called Merck defenses.

### F. Plaintiffs Are Entitled To Judgment As A Matter Of Law On Defendant's Damages Theories

No reasonable jury could accept Dr. Putnam's damages theory because Gilead presented no legally sufficient evidence to support it. Dr. Putnam's theory has no basis in law and does not mirror the type of hypothetical negotiation analysis the jury needs to determine a reasonable royalty.

Dr. Putnam impermissibly relied on post-hypothetical negotiation data, including data that would not be used by a reasonable licensee and reasonable licensor in the hypothetical negotiation construct. It is a bedrock principle of patent law that "the negotiation must be hypothesized as of the time infringement began" and reflect the "[parties'] state of mind at the time of the hypothetical negotiation." *Interactive Pictures Corp. v. Infinite Pictures, Inc.*, 274 F.3d 1371, 1384–85 (Fed. Cir. 2001). Dr. Putnam, however, based his damages theory on a number of events that occurred after the date of the hypothetical negotiation. Thus, on the date of the hypothetical negotiation, the parties could not possibly have had any of the financial data upon which his theory relies. Although the book of wisdom doctrine admits that post-hypothetical negotiation information is sometimes relevant to "expose to light the elements of value that were there from the beginning," this does not allow Dr. Putnam to consider events that no party at the hypothetical negotiation could have anticipated, such as Merck's acquisition of Idenix. *See Sinclair Ref. Co. v. Jenkins Petroleum Process Co.*, 289 U.S. 689, 698 (1933).

Dr. Putnam fatally failed to assume invalidity and infringement. Dr. Putnam applied a backwards analysis by testifying that the parties would negotiate a reasonable royalty based on the potential that the patents will not be found valid and infringed and then the parties would have adjusted the license from that basis.

Dr. Putnam's data bore no relation to the facts of this case. Dr. Putnam derived his royalty rate from a May 2000 case study that analyzed only the small fraction of patent cases that went to trial, and formulated a "certainty premium," based on the success rates of these cases, that he used to adjust his reasonable royalty rate. This stale and overly simplistic data set provides no reliable foundation for the hypothetical negotiation at issue. No reasonable jury could rely on Dr. Putnam's "certainty premium" to determine a royalty rate because Dr. Putnam's rate is not tied to any of the facts of this case.

Dr. Putnam then used incomparable licenses to testify that the parties would have structured the royalty as a lump-sum payment as opposed to a running royalty. Dr. Putnam relied on the Chiron settlement agreement for this theory, yet he ignored that: (1) the agreement had been a running royalty agreement for over a decade at the time of the hypothetical negotiation; (2) Gilead rejected two lump-sum agreements; and (3) Gilead negotiated the agreement under the threat of litigation. *See Panduit Corp. v. Stahlin Bros. Fibre Works*, 575 F.2d 1152, 1164 n.11 (6th Cir. 1978) ("A royalty…resulting from settlement of an infringement suit between Panduit and a third party[] should not be considered evidence…here. License fees negotiated in the face of a threat of high litigation costs may be strongly influenced by a desire to avoid full litigation.") (internal quotations omitted). Thus, Dr. Putnam's damages theories must be rejected as a matter of law.

## IV. CONCLUSION

For the reasons stated above, Plaintiffs are entitled to judgment as a matter of law that that Gilead has failed to prove the ’597 patent lacks written description; that Gilead has failed to prove the ’597 patent lacks an enabling disclosure; that Gilead has failed to prove the ’597 patent lacks utility; that the ’597 patent is entitled to a priority date of May 23, 2000; that Gilead has failed to prove the ’597 patent is anticipated or obvious over any prior art based on work conducted or patents filed by Merck; and that Gilead’s damages theory must fail.

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